Proposed Maximum Residue Limit PMRL2017-03

Prothioconazole

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing to establish a maximum residue limit (MRL) for prothioconazole on undelinted cotton seeds to permit the import and sale of foods containing such residues.

Prothioconazole is a fungicide currently registered in Canada for use on various commodities.

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when prothioconazole is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally established as an MRL on the corresponding imported commodity. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for prothioconazole is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRL can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for prothioconazole, is as follows.

Table 1 Proposed Maximum Residue Limit for Prothioconazole

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Prothioconazole	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3*H*-1,2,4-triazole-3-thione, including the metabolite α-(1-chlorocyclopropyl)-α-[(2-chlorophenyl)methyl]-1*H*-1,2,4-triazole-1-ethanol	0.4	Undelinted cotton seeds

[1] ppm = parts per million

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

The MRL proposed for prothioconazole in Canada is the same as the corresponding American tolerance as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there is no Codex MRL[1] listed for prothioconazole in or on undelinted cotton seeds on the Codex Alimentarius Pesticide Residues in Food and Feed webpage.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Undelinted cotton seeds	0.4	0.4	Not Established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRL for prothioconazole up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for prothioconazole in cotton were submitted to support the maximum residue limit on imported undelinted cotton seeds. In addition, a processing study in treated cotton was reviewed to determine the potential for concentration of residues of prothioconazole into processed commodities.

Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for prothioconazole and prothioconazole-desthio was based upon the residues observed in the crop commodity treated at exaggerated rates compared to the registered use rate in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for imported undelinted cotton seeds.

Table A1 Summary of Field Trial and Processing Data Used to Support MRL

Commodity	Application Method/ Total Application Rate (g a.i./ha)[1]	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Undelinted cotton seeds	Foliar/ 600-610	27-40	<0.04	0.26	Refined oil (0.12)

[1] g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover total residues of prothioconazole. Total residues of prothioconazole in the imported crop commodity at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.